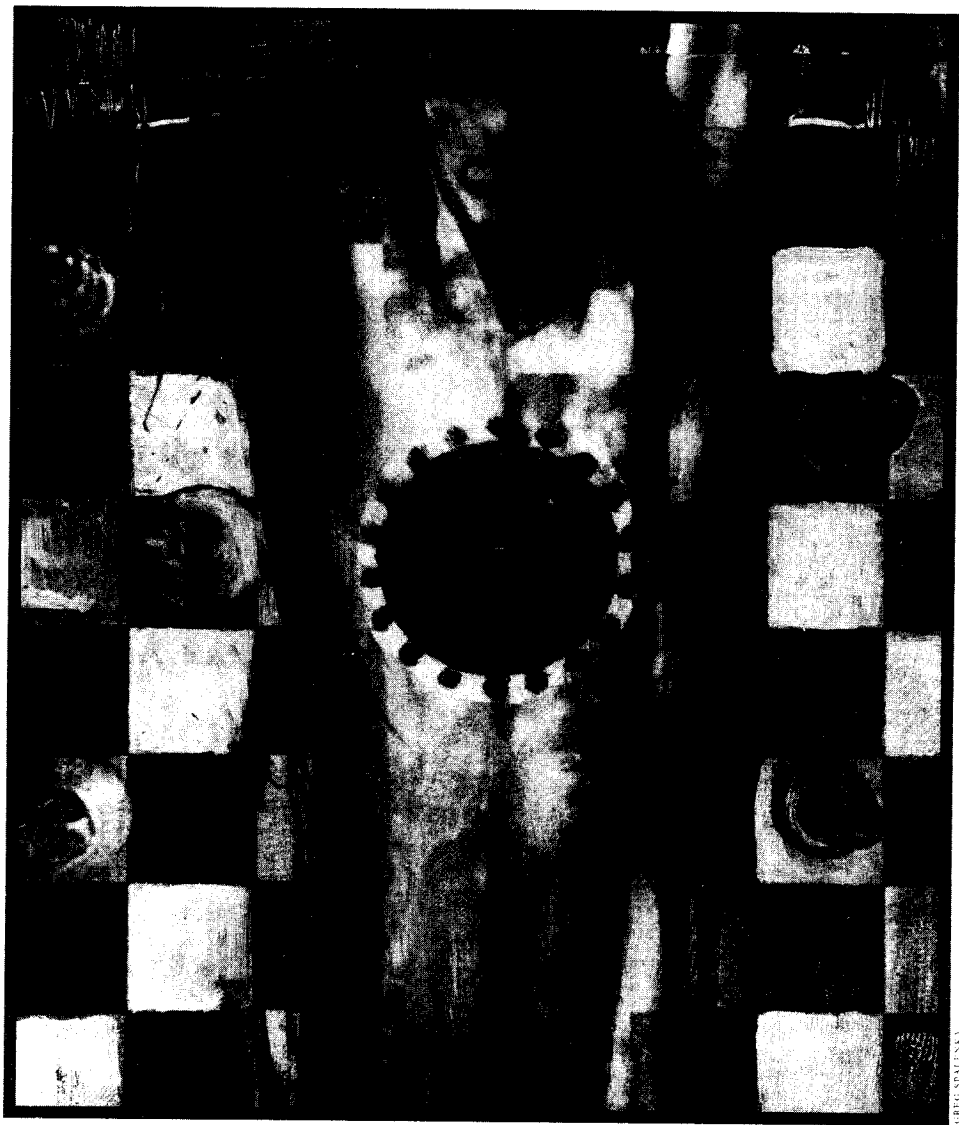


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TO STOP
HIV BY
ATTACKING
IT EARLY



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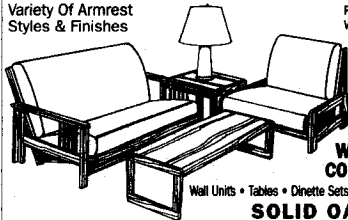
The symptoms seemed like a run-of-the-mill flu: achy muscles, nausea, a fever that spiked at 103. But “something just felt different,” recalls Peter, who asked that his real name not be used. His lymph nodes were swollen up the side of his neck like a row of “olive

BY MARK SCHOOFS



VOICE August 15, 1995

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pits." And he felt anxious about a "two-minute
lapse of judgment" during a sexual encounter a
couple of weeks earlier. He decided to see his
doctor.

Over the next few months, well before flu
season hits, hundreds of New Yorkers will feel
symptoms similar to Peter's. Most of these people,
and their doctors, will shrug off the illness.
Only a few will discover, as Peter did, that the
culprit is HIV and that their "flu" is what's called
conversion sickness: the body's unpleasant signal
that it has "converted" to being HIV-positive.

But Peter and 11 others will participate in
a small, fascinating trial, scheduled to start this

ponents emerge with slight differences from the
previous generation.

What Ho and Shaw discovered, in effect,
was that these new generations are produced with
lightning speed. And because each one is likely to
mutate, it isn't long before the swarm of virus cir-
culating in an individual's body contains countless
strains. In the first year, estimates Ho, the virus
can produce up to a million variations; in later
years, it's up to a billion. So when doctors ad-
minister an antiviral drug such as AZT, the virus
already has produced variants that drug will not
harm. These resistant strains replicate until they
are dominant, rendering the drug useless.

Similarly, HIV's prolific mutation may be

"IT'S A CHESS GAME," SAYS ONE SCIENTIST. "WE ARE TRYING TO CORNER THE VIRUS, BUT WE CAN'T SEE MANY MOVES IN ADVANCE."

month in New York. By catching people as soon
as possible after they've been infected, and then
administering three powerful drugs that target
HIV, researchers believe there's a slight chance
that HIV can be eliminated from the body.
Their more sober hope is that the virus can be
suppressed enough to defer the onset of AIDS,
perhaps for years.

"It isn't our intention to hype anything,"
cautions Dr. David Ho, director of the Aaron
Diamond AIDS Research Center, which is con-
ducting the trial. "We are not concocting the po-
tion that would cure AIDS."

But Ho and his colleague, Dr. Martin
Markowitz, are clearly excited. A recent revela-
tion about how HIV works in the body, along
with new and apparently more potent drugs,
suggest that early, aggressive treatment will
work. "It's a chess game," says Ho. "We are try-
ing to corner the virus, but we can't see that
many moves in advance. If we are lucky enough
to win, then great. But if we don't, I think un-
derstanding the moves the virus would make is
still pretty useful."

Three fundamental reasons prop-
elled Ho and his colleagues to
conduct this trial. First was a
widely heralded revelation, dis-
covered independently by Ho
and Dr. George Shaw of the University of Al-
abama at Birmingham, that HIV does not en-
ter a long dormant phase after infection, as was
previously believed. Instead, even though an in-
fected person may show no symptoms, HIV is
furiously active, replicating at up to 10 billion
viral particles per day. (The immune system is
also in high gear, trying to keep pace with the
virus and gradually losing.)

This discovery has profound ramifications.
Scientists have known for some time that HIV
is a highly mutable virus. When it infects an im-
mune system cell, HIV hijacks the cell's DNA,
turning it into a factory of viral RNA and pro-
teins. In this biological hijacking—carried out
by an enzyme called reverse transcriptase—small
genetic changes often occur and new viral com-

its greatest advantage against the body's natu-
ral defenses. In this month's *Scientific American*,
two scientists theorize that the immune system
can control several viral strains, but at some
point HIV's diversity "befuddles" the body's re-
sponse.

That leads to the second reason for con-
ducting the trial: For some time after infection—
just how long is unclear—the body's population
of HIV is homogenous. Then, says Ho, "the
clock begins to tick." The hope is that aggressive
treatment at this very early stage can stop the
clock—or at least slow it down.

To improve the odds, the researchers
are deploying three different drugs. The chance that
an individual virus would mutate in all the right
places to resist all three of the drugs, says Ho,
is roughly one in a trillion. The trial will use AZT
as well as two experimental medications: 3TC,
which has been shown to work well with AZT,
and ABT-538, one of a new class of drugs called
protease inhibitors, so named because they tar-
get a critical viral enzyme called protease. Early
experiments with ABT-538 suggest that it may
be considerably more powerful than the other
two drugs.

This is the third reason for conducting the
trial: Fourteen years into the AIDS epidemic,
there finally are medications that just might
make a difference. This experiment could shed
light on how to deploy them.

What can go wrong? Plenty. First, the
drugs could cause serious side effects, espe-
cially the newer ones, which simply haven't been
monitored for long-term consequences. (The
trial will last at least a year.) In combination, the
medicines might cause even worse problems
than they do individually.

To guard against this, all trial participants
will be hospitalized for at least one week, when
the drugs are first being administered. "I'm hop-
ing for a river view," quips Peter. Despite such
bravado, the specter of side effects scared him
enough to designate a health care proxy, and he's
told his younger brother about his recent infec-
tion "so my boyfriend won't have to tell my fam-
ily if something goes wrong."

"Nature is much more elegant than what we design," says Ho. "So we could be very, very surprised by the viral strategies." Peter's disease and death could even be accelerated.

Still, Peter has a "rational hope" along with a "fantastic hope." Although they don't use those terms, so do the researchers. The fantastic hope amounts to a cure, though everyone, even Peter, avoids that word. Instead, the researchers speak of "knocking out" the virus. "By that," says Ho, "I mean that we couldn't detect any form of active virus in the blood."

Could that happen? "It's possible, if the virus is homogenous enough, and if you prevent every last particle from infecting [immune cells]," says Dr. Robert Gallo, the co-discoverer of HIV. "I think it's theoretically possible. Do I think it will happen? No."

Even if viral particles were cleared from Peter's blood, he would not necessarily be cured. For reasons that remain murky, a small proportion of the immune system cells hijacked by HIV do not immediately produce new virus. Ho likens these cells to embers. If the "big fire" of active virus were put out, the embers of latent virus could still "reignite the whole process."

Eventually, if no virus, latent or active, can be found in Peter's body, he and Ho will have to face the question, "Do we pull the drugs and see what happens?" Gallo knows what he would do. Noting that individual HIV proteins are suspected of causing everything from Kaposi's Sarcoma and other cancers to brain damage, Gallo cautions that the embers of AIDS might never be extinguished: "If I have the right drug, I'm going to treat people forever."

If the virus can't be knocked out, it might be suppressed. This is the "rational hope," and it is based on the observation of so-called long-term nonprogressors, people who have lived with the virus and shown no symptoms for 15 years or more. They have a distinctive disease pattern.

Around the time of conversion sickness, the level of active virus particles in the blood spikes at a very high level for everyone. (The person is highly infectious then, more than at any time except near the end of the disease.) Then the "viral load" plunges down to a baseline level. The virus is still replicating furiously, but the body apparently is keeping it in check, forming a delicate but often long-lasting balance. During this time many infected people feel healthy and show few symptoms. In long-term non-progressors, the baseline viral load tends to be lower than in people who succumb to AIDS more quickly. What Ho hopes to do is shove Peter's baseline down to the level of a nonprogressor, and keep it there.

"The hard part of this study is the what-then question," says Dr. Deborah J. Cotton, a longtime AIDS researcher and clinician at Boston's Massachusetts General Hospital. "If this approach is absolutely stunning," then the obvious response would be to launch "an intensive effort to find people who are seroconverting, conceivably even an attempt to treat high-risk people before they get infected." But she adds, "It's more likely that we are going to see some drops in viral load, but not some kind of sterilization of the bloodstream." In that case, she warns, it isn't so clear that people should jump into this kind of therapy.

Why not? Because a decrease in viral load might not actually prolong life. It seems logical that less virus in the blood would mean less likelihood of disease. But viral load is merely a "surrogate marker," a sign of how HIV is progressing. And it may not be a reliable gauge.

Spencer Cox, a member of the AIDS-treatment watchdog group TAG, cites the infamous example of arrhythmia, in which the heart beats irregularly. Applying common sense, researchers assumed that arrhythmia was a surrogate mark-

er for cardiac failure. Two drugs were developed that suppressed arrhythmia quite effectively, but both drugs also caused fatal heart attacks. "If you just take out the word arrhythmia and put in the words viral burden," says Cox, "we're having the same conversation."

The only sure way to tell whether a drug works, he and Dr. Cotton assert, is to conduct large clinical trials that measure actual survival and disease progression—a painstaking process that takes years. Ho concedes that there are "very few clinical studies" that demonstrate a correlation between viral burden and actual health. But, he argues, "we have to go with our best understanding of the situation."

To Ho, that boils down to "preserving as much [of the immune system] as you can for as long as you can." Besides trusting the reliability of viral load, Ho believes HIV might damage the immune system permanently. He gives a hypothetical example of a patient whose CD4 count (a measure of important immune-system cells) bounces up from 50 to 300 after antiviral treatment. "We have reason to believe the cells that are coming back are not entirely functional," says Ho. "Clearly patients are improved—I don't want to give the wrong message. But it's not the same functional level that you would see in another patient" whose CD4 cells are on the way down.

The disagreement over surrogate markers, currently very hot among AIDS experts, may have a deeper, almost philosophical source: one's faith in our knowledge of AIDS. "We know quite a bit about the pathogenesis of this disease," Ho says, "and everything suggests that all the bad outcomes correlate" with viral load. On the same topic, Cotton says, "Our level of understanding is too primitive to say that."

Even if the trial proves HIV can be conquered if cornered soon enough, the immediate practical benefit will be limited. Catching people at the time of "acute conversion" is very difficult (the reason Ho is having trouble finding suitable candidates for his trial). Many infected people never get conversion sickness. For those who do, the common HIV test might be useless, because it detects antibodies that typically don't show up for six weeks or more. Ho thinks the viral population remains relatively homogenous for three to six months, but Gallo believes the clock might tick much faster. "There's an enormous difference between two hours and two weeks," Gallo says, adding that by "several weeks, the virus is established, I'm sure of it." To make immediate treatment feasible, "you'd need a simple test, like licking a lollipop that changes color if you're infected."

Nothing like that now exists. Peter needed an expensive high-tech test, called a PCR, to find the virus. The PCR can detect HIV about two weeks after infection, but it is not covered by Medicaid or most private insurance. Increasingly, AIDS afflicts the poor, who have little access to basic medical care. And of course, more than 90 per cent of the world's new infections are occurring in the Third World.

But an effective early therapy might well create a consumer demand big enough for the pharmaceutical industry to develop a cheaper and more sensitive test, perhaps even one that could be used at home. So far, most AIDS counselors recommend testing only tentatively, largely because AIDS is incurable. An effective early therapy would change that attitude.

No doubt many people would still find out that they're infected too late for early treatment. And those already living with HIV would not be helped. Still, this trial might prolong or even save lives, and Peter feels "fortunate" for that chance.

People who have been infected within the last three months and who want more information about this trial should call Dr. Martin Markowitz at (212) 725-0018.

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